

UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION

LAURIE DeNEUI and	)	CIV. 07-4172-KES
TERRY DeNEUI,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	ORDER DENYING IN PART
	)	AND GRANTING IN PART
DR. BRYAN WELLMAN and	)	DEFENDANTS' SECOND
WILSON ASFORA, P.C., d/b/a	)	MOTION FOR SUMMARY
Sioux Falls Neurosurgical	)	JUDGMENT
Associates,	)	
	)	
Defendants.	)	

Defendants, Dr. Bryan Wellman and Wilson Asfora, P.C., d/b/a Sioux Falls Neurosurgical Associates, move for summary judgment on all claims except for the claim that Dr. Wellman violated the standard of care by performing surgery on Laurie DeNeui when she was not an appropriate candidate for such surgery.<sup>1</sup> Plaintiffs, Laurie DeNeui and Terry DeNeui, oppose the motion. Defendants' motion is denied in part and granted in part.

**BACKGROUND**

This is a medical malpractice action arising out of an anterior cervical diskectomy and fusion that Dr. Wellman performed on Laurie DeNeui (DeNeui)

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<sup>1</sup> Defendants' briefs in support of their second motion for summary judgment do not address Count III, which asserts a respondeat superior claim against Sioux Falls Neurosurgical Associates, or Count IV, which asserts a loss of consortium claim. Thus, the court will not treat defendants' second motion for summary judgement as being directed towards those claims.

on October 18, 2005. Dr. Wellman used bone morphogenetic protein (BMP), a product that enhances bone growth, during the surgery.<sup>2</sup> DeNeui alleges that the use of BMP caused her to develop difficulty breathing, swallowing, and speaking after the surgery, symptoms that have left her permanently and totally disabled and unable to work. Plaintiffs filed suit against defendants, alleging that Dr. Wellman breached his duty to exercise reasonable skill and care by performing an unnecessary surgery and by using BMP during the surgery in a manner that was not approved by the Food and Drug Administration (FDA). Plaintiffs also allege that Dr. Wellman breached his duty to obtain DeNeui's informed consent by failing to inform her about the material risks associated with the surgery, including the use of BMP in a manner that was not approved by the FDA.<sup>3</sup>

## **DISCUSSION**

Summary judgment is proper “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The burden is initially placed on the

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<sup>2</sup> BMP is manufactured by Medtronic Sofamor Danek (Medtronic). It is placed in the body as part of INFUSE Bone Graft, a product made by Medtronic that contains BMP and an absorbable collagen sponge. Docket 108, Ex. 4. INFUSE Bone Graft is used in combination with a metallic cage implant called the LT-CAGE Lumbar Tapered Fusion Device. Docket 108, Ex. 16 at 2.

<sup>3</sup> The use of a drug or device that has received FDA approval in a manner that is not approved by the FDA is referred to as “off-label” use. See Kaderabek v. Mercy Health Servs., 2000 WL 34031868, at \*4 (N.D. Iowa July 13, 2000).

moving party to establish both the absence of a genuine issue of material fact and that such party is entitled to judgment as a matter of law. Id.; Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986) (“[A] party seeking summary judgment always bears the initial responsibility of . . . demonstrat[ing] the absence of a genuine issue of material fact.” (internal quotations omitted)).

Once the moving party has met its initial burden, the nonmoving party “may not rely merely on allegations or denials in its own pleading[.]” Fed. R. Civ. P. 56(e)(2). Rather, the nonmoving party must, “by affidavits or as otherwise provided in this rule[,] set out specific facts showing a genuine issue for trial.” Id. For purposes of summary judgment, the facts, and inferences drawn from those facts, are “viewed in the light most favorable to the party opposing the motion.” Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986) (quoting United States v. Diebold, Inc., 369 U.S. 654, 655 (1962)).

In determining whether a genuine issue for trial exists, the court applies the standard and burden associated with the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986) (“The judge’s inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict[.]”). South Dakota substantive law applies to the issues of medical negligence, informed consent, and punitive damages because this case is before the court on the basis of diversity. Hammonds v. Hartford Fire Ins. Co., 501 F.3d 991,

996 n.6 (8th Cir. 2007) (“We apply South Dakota substantive law because this diversity action was brought in the District of South Dakota, and the district court sitting in diversity applies the substantive law of the state in which it is located.” (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938))).

Defendants move for summary judgment with regard to three claims in the complaint: (1) that Dr. Wellman’s off-label use of BMP fell below the requisite standard of care; (2) that Dr. Wellman failed to obtain DeNeui’s informed consent; and (3) that plaintiffs are entitled to punitive damages.

**1. Breach of Professional Duty of Care**

Defendants argue that partial summary judgment is appropriate with regard to Count I, which alleges that Dr. Wellman breached his professional duty of care owed to DeNeui and was negligent in her medical care and treatment, because there is no evidence showing that BMP could have caused DeNeui’s alleged long-term injuries. In support of this argument, defendants correctly point out that the law in South Dakota generally requires that DeNeui present expert testimony that establishes causation. Koeniguer v. Eckrich, 422 N.W.2d 600, 601 (S.D. 1988) (“The plaintiff has the burden of proving causation in a malpractice action and generally must present expert testimony to meet this burden.”). Defendants argue that there is no reliable evidence showing that BMP caused DeNeui’s alleged permanent injuries because plaintiffs’ expert testimony is not sufficiently reliable to demonstrate causation. Defendants have raised this similar argument twice before in their motions to

exclude plaintiffs' expert testimony. (See Dockets 80, 81, 113, 141, 142, 154.) As set out in DeNeui v. Wellman, 2009 WL 3188414 (D.S.D. August 11, 2009), the court rejected defendants' argument that Dr. Dowdle's expert testimony should be excluded.<sup>4</sup> The reasoning and conclusion articulated in that ruling with regard to causation is incorporated into this order. See id. at \*5-7. Because defendants do not offer any additional arguments demonstrating that plaintiffs cannot show that BMP caused DeNeui's alleged onset injuries, defendants' motion for partial summary judgment of Count I is denied.

## **2. Failure to Obtain DeNeui's Informed Consent**

Defendants also move for summary judgment on Count II, which alleges that Dr. Wellman breached his professional duty to obtain DeNeui's informed consent. Defendants argue that Dr. Wellman could not have breached his duty to obtain DeNeui's informed consent by failing to tell DeNeui that BMP was going to be used off-label because, as a matter of law, a doctor has no duty to inform a patient of such off-label use. Plaintiffs argue that Dr. Wellman failed to obtain DeNeui's informed consent by failing to properly disclose all of the risks associated with the surgery, including the risks associated with the use of BMP in the cervical spine as warned by the manufacturer of BMP and otherwise known by Dr. Wellman.

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<sup>4</sup>The court also rejected defendants' similar argument with regard to their motion to exclude the expert testimony of Dr. Barrash and Dr. Watts.

In South Dakota, a physician generally owes a duty to obtain a patient’s informed consent before operating on that patient. Wheeldon v. Madison, 374 N.W.2d 367, 374 (S.D. 1985) (“We agree that the right to know—to be informed—is a fundamental right personal to the patient and should not be subject to restriction by medical practices that may be at odds with the patient’s informational needs.”). There is no dispute that DeNeui was Dr. Wellman’s patient. Therefore, as a matter of law, Dr. Wellman owed a duty to DeNeui to obtain her informed consent. See id.

In Wheeldon, the South Dakota Supreme Court established the applicable standard with regard to the issue of informed consent: “Accordingly, we adopt the Canterbury v. Spence rule that the standard measuring the performance of the physician’s duty to disclose is conduct which is reasonable under the circumstances.” Id. (citing Canterbury v. Spence, 464 F.2d 772, 785 (D.C. Cir. 1972)). The South Dakota Supreme Court elaborated that “a reasonable disclosure [is] one which appraises the patient of all known material or significant risks inherent in a prescribed medical procedure, as well as the availability of any reasonable alternative treatment or procedures.” Id. at 375 (citation omitted). “A risk is generally defined as material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or risks in deciding whether to submit to the proposed medical treatment or procedure.” Id. (citing Canterbury, 464 F.2d at 787) (other citations omitted). Whether risks are

“material” is a question that is to be answered by a jury. See *Canterbury*, 464 F.2d at 788 (“Whenever nondisclosure of particular risk information is open to debate by reasonable-minded men, the issue is for the finder of the facts.” (citations omitted)); *Sundberg v. Bubenik*, 2005 WL 6003548, at \*1 (D.S.D. Jun. 17, 2005) (“This information is relevant to assist the trier of fact in evaluating whether a reasonable person would have given informed consent.”); cf. *Waltner v. Educational Mut. Ben. Ass’n*, 284 N.W. 776, 778 (S.D. 1939) (stating that “there was no error in submitting the materiality of these facts to the jury” with regard to the defendant’s contention “that the insured misrepresented the condition of her health in her [insurance policy] application”).

Defendants argue that “the only issue is whether Dr. Wellman had a duty, as a matter of law, to advise Mrs. DeNeui that he intended to use an FDA-approved product, BMP, for an indication that has not been approved by the FDA.” (Mem. in Supp. of Defs.’ Mot. for Partial Summ. J., Docket 144, at 17.) In support of this argument, defendants note the apparent majority viewpoint that a physician does not have to inform a patient about an off-label use of an FDA-approved drug in order to obtain that person’s informed consent. See, e.g., *Blazoski v. Cook*, 787 A.2d 910 (N.J. Super. Ct. App. Div. 2002); *Southard v. Temple Univ. Hosp.*, 781 A.2d 101 (Pa. 2001); *Klein v. Biscup*, 673 N.E.2d 225 (Ohio Ct. App. 1996). Defendants rely heavily on an Ohio case in support of their argument and contend that Ohio’s standard with

regard to informed consent is akin to South Dakota's standard. The South Dakota Supreme Court, however, "adopt[ed] the Canterbury v. Spence rule that the standard measuring the performance of the physician's duty to disclose is conduct which is reasonable under the circumstances." Wheeldon, 374 N.W.2d at 374 (citing Canterbury, 464 F.2d at 785). According to Canterbury, "[w]henEVER nondisclosure of particular risk information is open to debate by reasonable-minded men, the issue is for the finder of the facts." Canterbury, 464 F.2d at 788.

Moreover, in South Dakota "[m]ateriality . . . is the cornerstone upon which the physician's duty to disclose is based." Wheeldon, 374 N.W.2d at 375. With regard to materiality, the South Dakota Supreme Court has stated that "a risk is generally defined as material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or risks in deciding whether to submit to the proposed medical treatment or procedure." Id. (emphasis added). The presence of a "reasonable person" standard indicates that the issue of the materiality of the off-label use of BMP is to be decided by a jury. Carlson v. Constr. Co., 761 N.W.2d 595, 599 (S.D. 2009) ("[T]he reasonable person standard . . . is determined by the evidence and decided by the jury."). Therefore, a jury must determine whether a reasonable person would attach significance to the off-label use of BMP before deciding whether to undergo the



surgery in this case.<sup>5</sup> See id.; Wheeldon, 374 N.W.2d at 375; Canterbury, 464 F.2d at 788 (“Whenever nondisclosure of particular risk information is open to debate by reasonable-minded men, the issue is for the finder of the facts.” (citations omitted)). See also Blazoski, 787 A.2d at 921 (“Understandably, in this case the trial court permitted the jury to consider whether the FDA status was material to a prudent patient’s decision to undergo the spinal fusion procedure.”).

One of DeNeui’s experts, Dr. Barrash, states that “[w]hen an unapproved product is used, it is the responsibility of the physician to give the patient all the information available and the alternatives to the use of that product to allow that patient to make the value judgment as to whether they do or do not wish to have that product used.” (Dr. Barrash Report, Docket 119-2, at 1.) Dr. Barrash further states that “[t]he complications of this product were clearly known and directives were clearly written as to the problems that could arise.” (Id.) A jury could therefore reasonably conclude that under the circumstances,

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<sup>5</sup> Defendants’ reliance on Blazoski is misplaced because there the court addressed the issue of “whether a surgeon must inform a spinal-fusion patient that the internal fixation device he intends to utilize during surgery was not approved by the [FDA] for use on the lumbar spine.” Blazoski, 787 A.2d at 913 (emphasis added). That is, the argument that a physician must always inform a patient about the off-label use of an FDA approved device was rejected. Id. at 921 (“We hold that defendant was not required to disclose to plaintiff the FDA investigational status of pedicle screws in order for plaintiff to have given an informed consent to the surgery.”). Here the issue is whether the physician should have informed plaintiffs of off-label use of BMP under the facts of this case, not whether such disclosure is required in all cases.

a reasonable person would need to have been informed about BMP's off-label use in order to give informed consent. Thus, summary judgment is inappropriate because there is a material question of fact as to whether the failure to inform DeNeui about the off-label use of BMP constituted a failure to disclose a material risk.

Moreover, whether Dr. Wellman had a duty to disclose that BMP would be used off-label is not the only issue with regard to whether Dr. Wellman breached his duty to obtain DeNeui's informed consent. Plaintiffs contend that Dr. Wellman also failed to disclose other material risks associated with the surgery. There are numerous ways for a physician to breach the duty to obtain a patient's informed consent. See generally *Veith v. O'Brien*, 739 N.W.2d 15, 32 (S.D. 2007) (citing *Savold v. Johnson*, 443 N.W.2d 656 (S.D. 1989); *Wheeldon v. Madison*, 374 N.W.2d 367 (S.D. 1985); *Alberts v. Giebink*, 299 N.W.2d 454 (S.D. 1980); *Cunningham v. Yankton Clinic, P.A.*, 262 N.W.2d 508 (S.D. 1978), abrogated on other grounds by SDCL 15-2-14.3 (1979)). Thus, even if Dr. Wellman did not have a duty to disclose the off-label use of BMP, DeNeui's claim of lack of informed consent would survive summary judgment if Dr. Wellman failed to disclose other material risk information. See *Wheeldon*, 374 N.W.2d at 375 (“[W]e deem a reasonable disclosure to be one which apprises the patient of all known material or significant risks inherent in a prescribed medical procedure, as well as the availability of any reasonable alternative treatment or procedures.” (emphasis added)).

Viewing the facts in the light most favorable to the non-moving party, DeNeui was not properly informed by either Dr. Wellman or his staff about other material risks associated with her surgery. (Laurie DeNeui Dep., Docket 150-4, at 37, 41 (responding to questions as follows: “I’m saying I don’t think [Dr. Wellman] talked to me about specific risks;” and “I don’t believe [the nurse] told me any risks”). A jury could therefore reasonably find that Dr. Wellman did not obtain DeNeui’s informed consent if it determines that DeNeui was never properly informed about any of the other material risks associated with her surgery. Because there is a material question of fact as to whether Dr. Wellman disclosed all material risks, summary judgment is inappropriate. See Alberts, 299 N.W.2d at 456 (“The record below is inconclusive as to defendants’ level of disclosure. . . . [W]e cannot determine whether defendants breached this duty.”).

Defendants argue that the risks associated with the surgery were the same regardless of whether BMP was used and that it is undisputed that DeNeui was made aware of the risks because she was given a booklet about the types of risks associated with the surgery without BMP.<sup>6</sup> Prior to conducting this surgery, Dr. Wellman was aware of manufacturer warnings about certain complaints associated with off-label use of BMP in anterior cervical fusion procedures. Thus, there is a question of material fact as to whether

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<sup>6</sup> DeNeui admits that she was given a booklet that listed the general risks of the surgery prior to her surgery. (Docket 146-2, at 2.)

Dr. Wellman conducted himself in such a manner to adequately inform DeNeui and obtain her informed consent. That is, the jury must determine whether giving DeNeui a booklet that outlined the general risks associated with the surgery without the use of BMP was reasonable under the circumstances when the surgery involved the use of BMP. Compare Wheeldon, 374 N.W.2d at 374 (noting that “the standard measuring the performance of the physician’s duty to disclose is conduct which is reasonable under the circumstances”) with Carlson, 761 N.W.2d at 599 (noting “that the reasonable person standard . . . is determined by the evidence and decided by the jury”).

With regard to Count II, defendants argue that summary judgment must be granted because DeNeui cannot show that the failure to disclose the material risks caused the alleged harms. Defendants argue that plaintiffs cannot establish causation because their expert testimony is inadmissible as being speculative and unreliable. The court denied defendants’ motion in limine to preclude the testimony of plaintiffs’ expert witnesses on the causation issue. Because the evidence is admissible, a jury could reasonably accept the expert testimony that the off-label use of BMP caused her injuries. Moreover, a jury could reasonably conclude that the other allegedly undisclosed material risks occurred and caused DeNeui’s injuries.

Defendants’ motion for summary judgment on Count II is therefore denied because there is a material issue of fact as to whether Dr. Wellman

breached his duty to obtain DeNeui's informed consent by failing to disclose all of the material risks associated with a surgery.

### **3. Punitive Damages**

Defendants argue they are entitled to summary judgment on the claim for punitive damages because there is no evidence showing that Dr. Wellman intended or desired to injure DeNeui or that Dr. Wellman acted willfully or wantonly in injuring DeNeui. Plaintiffs argue that Dr. Wellman knew of the material risks associated with the off-label use of BMP and deliberately chose to keep that information from DeNeui.

Under South Dakota law,

[i]n any action for the breach of an obligation not arising from contract, where the defendant has been guilty of oppression, fraud, or malice, actual or presumed, . . . committed intentionally or by willful and wanton misconduct, in disregard of humanity, the jury, in addition to the actual damage, may give damages for the sake of example, and by way of punishing the defendant.

SDCL 21-3-2. "Malice is an essential element of a claim for punitive damages" in South Dakota. Isaac v. State Farm Mut. Auto. Ins. Co., 522 N.W.2d 752, 761 (S.D. 1994). Malice can be "either actual, malice in fact, or presumed, legal malice." Id. at 761. "Actual malice is a positive state of mind, evidenced by the positive desire and intention to injure another, actuated by hatred or ill-will towards that person." Id. (citation omitted). Presumed malice is that "which the law infers from or imputes to certain acts." Id. (citations omitted). "[W]hile the person may not act out of hatred or ill-will, malice may

nevertheless be imputed if the person acts willfully or wantonly to the injury of the other.” Id.

“Willful and wanton misconduct demonstrates an affirmative, reckless state of mind or deliberate recklessness on the part of the defendant.” Tranby v. Brodock, 348 N.W.2d 458, 461 (S.D. 1984). “A claim for presumed malice can be shown by demonstrating a disregard for the rights of others.” Isaac, 522 N.W.2d at 761 (citations omitted). Negligence by itself, however, “is not equivalent to willful and wanton misconduct.” Brown v. Youth Servs. Int’l of S.D., Inc., 89 F. Supp. 2d 1095, 1107 (D.S.D. 2000); see also Tranby, 348 N.W.2d at 461 (“Willful and wanton misconduct means something more than negligence.”). “South Dakota has one of the most strict conduct requirements for purposes of punitive damages. The conduct must be with malice, which is a more stringent requirement than gross negligence or even conduct that is more egregious than gross negligence.” Benson v. Giordano, 2008 WL 2390835, \*4 (D.S.D. Jun. 9, 2008). In the context of a negligence claim, the South Dakota Supreme Court has stated that:

There must be facts that would show that defendant . . . intentionally failed to do something which he should have done under the circumstances that it can be said that he consciously realized that his conduct would in all probability, as distinguished from possibility, produce the precise result which it did produce and would bring harm to the plaintiff.

Berry v. Risdall, 576 N.W.2d 1, 9 (S.D. 1998) (quoting Tranby, 348 N.W.2d at 461).

Plaintiffs argue that Dr. Wellman’s failure to obtain DeNeui’s informed consent for the off-label use of BMP in her cervical spine was willful, deceptive, and recklessly indifferent to her rights. Plaintiffs’ claim for punitive damages therefore stems from the allegation that Dr. Wellman needed to inform DeNeui about the off-label use of BMP in order to obtain her informed consent. In South Dakota, a claim premised on a lack of informed consent is essentially a claim of negligence. See Wheeldon, 374 N.W.2d at 376 (noting that “a breach of the physician’s duty” and causation must be demonstrated in order to recover under an informed consent claim). As noted in Grynberg v. Citation Oil & Gas Corp., 573 N.W.2d 493 (S.D. 1997), however, “[p]unitive damages are not available for most negligence actions.” Id. at 506 n.10 (citation omitted). Thus, in order for plaintiffs to recover punitive damages, there must be some facts showing that Dr. Wellman failed to inform DeNeui about the off-label use of BMP while “consciously realiz[ing] that his conduct would in all probability, as distinguished from possibility, produce the precise result which it did produce and would bring harm to the plaintiff.” See Berry, 576 N.W.2d at 9 (quoting Tranby, 348 N.W.2d at 461).

Viewing the facts in the light most favorable to plaintiffs, Dr. Wellman knew that using BMP in the cervical spine was not approved by the FDA, that the safety of using BMP in the cervical spine had not been established, that “some cases of edema, [swelling,] have been reported,” and that some of those reported cases involved swelling that was “severe enough to produce airway

compromise, sometimes requiring emergency surgery.” (Dr. Wellman Dep., Docket 150-5, at 36-38.) Dr. Wellman also failed to tell DeNeui anything about BMP except that it was going to be used in her surgery. (Laurie DeNeui Dep., Docket 150-4, at 37, 41.)

There are no facts, however, demonstrating that Dr. Wellman was aware that, in all probability, DeNeui’s injuries were likely to occur because he used BMP in the cervical spine. The only evidence identified by plaintiffs that demonstrates that Dr. Wellman knew about the risks associated with using BMP in the cervical spine was that Dr. Wellman had knowledge that “some” cases of swelling had been reported when BMP was used in a cervical spine surgery, and that “some” of those cases involved “airway compromise, sometimes requiring emergency surgery.” (Dr. Wellman Dep., 150-5, at 36.) Knowledge that there is “some” chance of a complication is tantamount to knowledge of there being a “possibility” of complications, but it cannot be construed as Dr. Wellman having knowledge that “in all probability” DeNeui’s injuries would result. See Tranby, 348 N.W.2d at 462 (noting that “there is no evidence from which a jury could find that defendant’s conduct was of such a nature that in all probability, as distinguished from possibility, an accident would occur.” (emphasis added)). Even DeNeui’s experts acknowledge that DeNeui’s alleged injuries could be one of the first cases of such injuries attributable to BMP because of its relatively brief existence. (Dr. Watts Dep., Docket 150-2, at 61-62 (answering yes to the question that “if Mrs. DeNeui’s



symptoms are due to the use of BMP, she's the first case that you would be aware of?"); (Dr. Barrash Dep., Docket 150-3, at 88 ("[DeNeui is] one of the early people that had a complication such as this.") Moreover, the literature, which appears to demonstrate that the complications associated with the off-label use of BMP in the cervical spine appear more often than with standard surgery, was published after DeNeui's surgery.<sup>7</sup> (Dr. Watts Dep., Docket 150-2, at 44-45); (Dr. Barrash Dep., Docket 150-3, at 79); (Dr. Wellman Dep., Docket 150-5, at 40.).

Based on these undisputed facts, there is no material factual dispute as to whether Dr. Wellman acted with malice because there are no facts showing that Dr. Wellman consciously realized that his failure to inform DeNeui about the material risks of using BMP in the cervical spine "would in all probability" result in DeNeui's alleged injuries. See Tranby, 348 N.W.2d at 462 (noting that "[t]he facts in this case are far apart from those that deal with . . . disregarding

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<sup>7</sup> DeNeui's surgery was on October 18, 2005. While there was an article published in May of 2005, the article does not discuss the potential for complications with the off-label use of BMP. Rather, that article discusses how BMP is associated with good fusion rates. (Dr. Barrash Dep., Docket 150-3, at 51-52.) Additionally, there was an article published in 2003 about using BMP in the cervical spine. But rather than indicating that the use of BMP in the cervical spine was associated with particular risks, the article says that the "pilot study demonstrates that the use of [BMP] in an anterior cervical fusion application is sufficiently safe for its use to be studied in a larger clinical trial." (David S. Baskin, MD et al., A Prospective, Randomized, Controlled Cervical Fusion Study Using Recombinant Human Bone Morphogenetic Protein-2 With the CORNERSTONE-SR™ Allograft Ring and the ATLANTIS™ Anterior Cervical Plate, 28 Spine 1219, 1224, Docket 146-9.)

warnings of obviously hazardous circumstances” and that “there is no evidence from which a jury could find that defendant’s conduct was of such a nature that in all probability, as distinguished from possibility, an accident would occur.” (emphasis added)). Cf. Berry, 576 N.W.2d at 9 (“This is a problem drinker who has been amply educated and warned as to the dangers of drinking and driving and has made a conscious choice to continue to do so anyway.”); Holmes v. Wegman Oil Co., 492 N.W.2d 107, 113 (S.D. 1992) (upholding an award of punitive damages where the defendant “knew of the potential danger of explosion from the control knob for ten years prior to deciding to recall it”); Flockhart v. Wyant, 467 N.W.2d 473, 478 (S.D. 1991) (“[The defendant] must have known, with substantial certainty, the danger which her conduct engendered.”).<sup>8</sup> Because there are no facts showing that Dr. Wellman acted with the requisite malice, defendants’ motion for partial summary judgment is granted with regard to plaintiffs’ claim for punitive damages.

Defendants also contend that plaintiffs’ response to this motion was untimely. Rule 6(a) of the Federal Rules of Civil Procedure provides that when

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<sup>8</sup> Plaintiffs observe that Dr. Wellman is still not telling his patients that BMP has not been approved by the FDA for use in the cervical spine. (Dr. Wellman Dep., Docket 150-5, 69-70.) Plaintiffs correctly point out that one purpose of punitive damages is to deter similar behavior in the future. See Gross v. Kouf, 349 N.W.2d 652, 654 (S.D. 1984). But Dr. Wellman’s current behavior does not demonstrate that he acted with any malice when treating DeNeui.

computing time, “the day of the act, event, or default that begins the period” is to be excluded. Fed. R. Civ. P. 6(a)(1). The “last day of the period” is to be included “unless it is a Saturday, Sunday, or legal holiday[.]” Fed. R. Civ. P. 6(a)(3). Also, three days are added for service after the time period would otherwise expire. Fed. R. Civ. P. 6(d).

Defendants filed their motion on April 3, 2009. Twenty days from April 3, excluding April 3, is April 23.<sup>9</sup> With the addition of three days for service, the time period to respond was April 26. Because April 26, 2009, was a Sunday, that day is excluded under Rule 6(a)(3). Thus, DeNeui needed to respond on or before April 27, 2009. While DeNeui did not respond until April 28, 2009, defendants have not argued that they were prejudiced in any way by DeNeui’s filing of the response one day late. See Dall v. United States, 957 F.2d 571, 572 (8th Cir. 1992) (“[T]he district court did not abuse its discretion by considering the governemnt’s response to [the defendant’s] section 2255 motion, even though it was filed four days late. . . . [The defendant] has not indicated how he was prejudiced by the government’s untimely filing.” (citation omitted)). Thus, the court will consider plaintiffs’ response.

Accordingly, it is hereby

ORDERED that defendants’ motion for partial summary judgment (Docket 143) is denied as to Counts I and II;

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<sup>9</sup> Plaintiffs had twenty days to respond to defendants’ motion. See D.S.D. Civ. LR 7.2(A).

IT IS FURTHER ORDERED that defendants' motion for partial summary judgment (Docket 143) is granted as to plaintiffs' claim for punitive damages.

Dated December 9, 2009.

BY THE COURT:

*/s/ Karen E. Schreier*

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KAREN E. SCHREIER  
CHIEF JUDGE